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DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/033,662	03/03/98	HU	J 1488.1040001

HM22/0610
STERNE KESSLER GOLDSTEIN & FAX
1100 NEW YORK AVENUE N W
SUITE 600
WASHINGTON DC 20005-3934

EXAMINER

SAQUD, C

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 06/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/033,662

Applicant(s)
HU et al.

Examiner
Christine Saoud

Group Art Unit
1646



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 26-65 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 26, 28, 30-34, 36, 38, 40, 42-46, 48, 50, 52, 53, 55, 57, 59, 61, 62, and 64 are allowed.

☒ Claim(s) 27, 29, 35, 37, 39, 41, 47, 49, 51, 54, 56, 58, 60, 63, and 65 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 and 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1646

DETAILED ACTION

1. Preliminary amendments were received in the instant application on 03 March 1998 (papers #5 and 6), 26 May 1998 (paper #7), and 08 April 1999 (paper #8). Claims 26-65 are currently pending in the instant application (the claims which were filed in paper #8).

Specification

2. The attempt to incorporate subject matter into this application by reference to the previously filed applications by amendment in paper #5 is improper because it is not in conformance with M.P.E.P. 608.04(b) because the amendment was not part of the original disclosure. Such amendment does not enjoy the status as part of the original disclosure in an application filed under 37 CFR 1.53 unless it is referred to in the oath or declaration filed therewith. Once an oath or declaration is submitted in an application filed under 37 CFR 1.53 identifying the papers which the inventor(s) has "reviewed and understands" as required by 37 CFR 1.63, the original disclosure of the application is defined and cannot be altered merely by filing of a subsequent oath or declaration referring to different papers. If the application is filed without an executed oath or declaration pursuant to 37 CFR 1.53(b), the original oath or declaration submitted later than the filing date must refer to the preliminary amendment filed along with the application in order to comply with 37 CFR 1.63. The recitation "which disclosure is herein incorporated by reference" should be deleted from the continuing data since it is new matter.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27, 29, 35, 37, 39, 41, 47, 49, 51, 54, 56, 58, 60, 63, and 65 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention appears to employ novel vectors and/or microorganisms. Since the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 USC § 112 may be satisfied by a deposit of the plasmid and/or microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the DNA sequences and/or microorganism are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids and/or microorganisms should have been made in accordance with 37 C.F.R. 1.801-1.809.

If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and

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registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Allowable Subject Matter

5. Claims 26, 28, 30-34, 36, 38, 40, 42-46, 48, 50, 52-53, 55, 57, 59, 61-62, and 64 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 8, 1999

**CHRISTINE SAOUD
PATENT EXAMINER**

Christine Saoud